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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,140	11/25/2003	Johan Wilhelm Stjernschantz	PC30246J	9449

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EXAMINER	
KOSACK, JOSEPH R	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,140	STJERNSCHANTZ ET AL.	
	Examiner	Art Unit	
	Joseph Kosack	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-38* is/are pending in the application.

4a) Of the above claim(s) *25-28 and 30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/469,442.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24-38 are pending in the instant application.

Election/Restrictions

Applicant's election without traverse of claims 24 and 29 in the reply filed on October 25, 2005 is acknowledged. Claims 25-28 and 30-38 have been withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

Priority

The claim to priority as a continuation of US Serial Number 10/330,846, abandonded, filed on December 27, 2002, which is a continuation of US Serial Number 10/106,228, abandoned, filed on March 27, 2002, which is a continuation of US Serial Number 09/781,896, now USPN 6,417,230, filed on February 12, 2001, which is a continuation of US Serial Number 09/307,813, now USPN 6,187,813, filed on May 10, 1999, which is a continuation of US Serial Number 08/461,341, abandoned, filed on June 6, 1995, which is a divisional of US Serial Number 07/986,943, now USPN 5,422,368, filed on December 8, 1992, which is a continuation of US Serial Number 07/469,442, abandoned, filed on April, 10, 1990, which is a 371 of PCT/SE89/00475, filed on September 8, 1989, and claims priority to Sweden Application 8803110-9, filed on September 6, 1988 and Sweden Application 8803855-9, filed on October 28, 1988, has been acknowledged for the instant application.

Information Disclosure Statement

The Information Disclosure Statement that was received on November 25, 2003 has been considered fully by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (USPN 4011262) in view of Boeckman et al. (*J. Org. Chem. 1986*, 5489-5490).

The instant application teaches 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$-isopropylester.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hess et al. teach 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$. See Column 34, lines 56-69.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Hess et al. do not teach the esterification of 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Boeckman et al. teach the esterification of a carboxylic acid by refluxing azeotropically with benzyl alcohol and p-toluenesulfonic acid in benzene. See page 5490, column 1, lines 5-7.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to take the compound of Hess et al. and esterify according to Boeckman et al. to make any number of alkyl esters. The motivation to do so is provided by Boeckman et al.. Boeckman et al. teach the protection of a carboxylic acid by esterification to carry on further synthesis, followed by deprotection to regenerate the carboxylic acid. See page 5490, column 1, lines 5-7, and column 2, lines 2-7.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (USPN 4011262) in view of Boeckman et al. (*J. Org. Chem. 1986*, 5489-5490) and Beitch et al. (*Br. J. Pharmac, 1969*, 158-167).

The instant application teaches a therapeutic composition containing 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$-isopropylester and an ophthalmologic compatible vehicle.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hess et al. teach 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$. See Column 34, lines 56-69.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Hess et al. do not teach the esterification of 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$ or the combination with an ophthalmologic compatible vehicle.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Boeckman et al. teach the esterification of a carboxylic acid by refluxing azeotropically with benzyl alcohol and p-toluenesulfonic acid in benzene. See page 5490, column 1, lines 5-7.

Beitch et al. teach a prostaglandin solution for injection into the eye. See page 159, paragraph 3 of the Methods section.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to take the compound of Hess et al., esterify according to Boeckman et al. to make any number of alkyl esters, and dissolve the new

compound in an ophthalmologic compatible vehicle. The motivation to do so is provided by Boeckman et al. and Beitch et al. Boeckman et al. teach the protection of a carboxylic acid by esterification to carry on further synthesis, followed by deprotection to regenerate the carboxylic acid. See page 5490, column 1, lines 5-7, and column 2, lines 2-7. Beitch et al. teach the injection of prostaglandins into rabbit eyes to increase intraocular pressure. See page 158, paragraph starting with "Injections."

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 29 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 and 47-50 of U.S. Patent No.

5,422,368 to Stjernschantz et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. Stjernschantz et al. teach a therapeutic composition containing 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_{2\alpha}$-isopropylester and an ophthalmologic compatible vehicle in claims 19-22 and 47-50 of the patent. Therefore, Stjernschantz et al. suggest the instant invention.

Conclusion

Claims 24 and 29 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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